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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,916	10/10/2001	Peter M. Thule	US 1292/01 (VA)	4645

7590 04/02/2009

Law Office - Dinesh Agarwal, P.C.
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Alexandria, VA 22312

EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
04/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/972,916	THULE, PETER M.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 12/16/2008.

In view of the response filed on December 16, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/JD Schultz/

Supervisory Patent Examiner, Art Unit 1635

Status if the Claims

Claims 1-15 and 17-21 are currently pending.

Claims 17-21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/21/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Diabetes May 1999, supplement— previously cited) as evidenced by Thule and Liu presentation at the ADA 59th Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743).

The instant claims are drawn to an insulin regulator construct comprising a nucleotide sequence as set forth in any one of SEQ ID NOS: 3-6 (each of which comprises a GIRE of the L-PK gene promoter and an insulin sensitive element of the IGFBP-1 basal promoter) and a sequence encoding insulin or proinsulin operably linked to the promoter element of the construct (e.g., see claim, 1 and 9); wherein the GIRE comprises an HNF-4 binding site and a glucose responsive site (claim 2); wherein the construct comprises a plurality of GIREs (claim 3); wherein the HNF-4 binding site and the GIRE are in a native orientation (claim 4); wherein the

HNF-4 binding site and the GIRE are reversed from a native orientation (claim 5); wherein the GIRE is upstream of the insulin sensitive element (claim 6); wherein the GIRE comprises a nucleotide sequence as set forth in SEQ ID NO: 1 (claim 7); wherein the insulin sensitive element comprises a nucleotide sequence as set forth in SEQ ID NO: 2 (claim 8); wherein the construct is not stimulated by lactate or sucrose (claim 10); wherein glucose stimulates expression of the construct and wherein insulin inhibits expression the construct (claim 11); wherein the construct is comprised in a vector (claim 12); wherein the vector is an adenoviral vector (claim 13); wherein the construct comprises a transgene (claim 14); and wherein the construct is comprised in a pharmaceutical composition with a pharmaceutically acceptable carrier or diluent (claim 15).

It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/$(GIRE)_3$BP-1 2xfur (which is an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

Thule (Diabetes) is an abstract from a presentation that the inventor gave more than one year before the effective filing date of the instant application. The abstract teaches an adenoviral vector which is described as comprising all of the claimed elements, and which also named Ad/$(GIRE)_3$BP-1 2xfur. Since the Ad/$(GIRE)_3$BP-1 2xfur vector taught by the Thule (Diabetes) abstract appears to be the same vector described in the specification, it would necessarily meet all of the structural limitations of the claims. Furthermore, in the presentation given by the Inventor at the ADA 59th Annual Meeting June 1999, which is the presentation associated with the Thule (Diabetes) abstract, the slides (e.g., see slides 2 and 3) clearly describe the elements

used to construct the Ad/$(GIRE)_3$BP-1 2xfur vector. Specifically, the slides indicate the exact nucleotides of the rL-PK (nucleotides –125 to –173) and rIGFBP-1 (nucleotides –111 to +96) promoter elements used to construct the vector. Furthermore the nucleotide sequences of the rL-PK and rIGFBP-1 promoter elements were known in the art, as evidenced by Vaulont et al (see Figure 9 which discloses nucleotides –125 to -173 of rL-PK) and Goswami et al (See Figure 3A which discloses nucleotides –111 to +96 of rIGFBP-1). Therefore, the Thule abstract, as evidenced by the Thule presentation and as further evidenced by Vaulont et al and Goswami et al, provides an enabling disclosure which teaches the claimed invention. Accordingly, the instant claimed invention was described in a printed publication in this country more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting June 9-13, 1999, previously cited) as evidenced by Thule and Liu presentation at the American Society of Gene Therapy 2nd Annual Meeting, June 1999 (provided as Reference 4 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743).

The instant claims are described above.

It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/$(GIRE)_3$BP-1 2xfur (which is an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

The Thule abstract is an abstract from a presentation that the inventor gave more than one year before the effective filing date of the instant application. The abstract teaches an adenoviral vector which is described as comprising all of the claimed elements, and which also named Ad/$(GIRE)_3$BP-1 2xfur. Since the Ad/$(GIRE)_3$BP-1 2xfur vector taught by Thule appears to be the same vector described in the specification, it would necessarily meet all of the structural limitations of the claims. Furthermore, in the presentation given by the Inventor at the American Society of Gene Therapy 2nd Annual Meeting June 1999, which is the presentation associated with the Thule abstract, the slides (e.g., see slides 3 and 4) clearly describe the elements used to construct the Ad/$(GIRE)_3$BP-1 2xfur vector. Specifically, the slides indicate the exact nucleotides of the rL-PK (nucleotides –125 to –173) and rIGFBP-1 (nucleotides –111 to +96) promoter elements used to construct the vector. Furthermore the nucleotide sequences of the rL-PK and rIGFBP-1 promoter elements were known in the art, as evidenced by Vaulont et al (see Figure 9 which discloses nucleotides –125 to -173 of rL-PK) and Goswami et al (See Figure 3A which discloses nucleotides –111 to +96 of rIGFBP-1). Therefore, the Thule abstract, as evidenced by the Thule presentation and as further evidenced by Vaulont et al and Goswami et al, provides an enabling disclosure which teaches the claimed invention. Accordingly, the instant claimed invention was described in a printed publication in this country more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting of June 1998—previously cited) as evidenced by Thule and Liu presentation at the ADA 58th Annual Meeting, June 1998 (provided as Reference 2 in the IDS

filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743).

The instant claims are described above.

It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/$(GIRE)_3$BP-1 2xfur (which is an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

The Thule abstract is an abstract from a presentation that the inventor gave more than one year before the effective filing date of the instant application. The abstract teaches an adenoviral vector which is described as comprising all of the claimed elements, and which also named Ad/$(GIRE)_3$BP-1 2xfur. Since the Ad/$(GIRE)_3$BP-1 2xfur vector taught by the Thule abstract appears to be the same vector described in the specification, it would necessarily meet all of the structural limitations of the claims. Furthermore, in the presentation given by the Inventor at the ADA 58th Annual Meeting June 1998, which is the presentation associated with the Thule abstract, the slides (e.g., see slides 3, 4 and 14) clearly describe the elements used to construct the Ad/$(GIRE)_3$BP-1 2xfur vector. Specifically, the slides indicate the exact nucleotides of the rL-PK (nucleotides –125 to –173) and rIGFBP-1 (nucleotides –111 to +96) promoter elements used to construct the vector. Furthermore the nucleotide sequences of the rL-PK and rIGFBP-1 promoter elements were known in the art, as evidenced by Vaulont et al (see Figure 9 which discloses nucleotides –125 to -173 of rL-PK) and Goswami et al (See Figure 3A which discloses nucleotides –111 to +96 of rIGFBP-1). Therefore, the Thule abstract, as evidenced by the Thule presentation and as further evidenced by Vaulont et al and Goswami et al, provides an enabling

disclosure which teaches the claimed invention. Accordingly, the instant claimed invention was described in a printed publication in this country more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thule et al (Diabetes May 1999, supplement— previously cited) in view of Thule and Liu presentation at the ADA 59th Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and further in view of Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Cognet et al. (J. Mol. Biol. 1987, cited by Applicants).

The instant claims are described above.

It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/(GIRE)$_3$BP-1 2xfur (which is an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

To the extent that Thule (Diabetes) does not explicitly teach the actual claimed nucleotide sequences, the claims are obvious in view of the cited prior art for the following reasons.

As indicated above, Thule (Diabetes) is an abstract from a presentation that the inventor gave more than one year before the effective filing date of the instant application. The abstract teaches an adenoviral vector which is described as comprising all of the claimed elements, and which also named Ad/$(GIRE)_3$BP-1 2xfur. The Ad/$(GIRE)_3$BP-1 2xfur vector taught by the Thule (Diabetes) abstract appears to be the same vector described in the specification, which would necessarily have the same structure; however, the Thule (Diabetes) reference does not provide the actual nucleotide sequence of the promoter element(s) of the vector.

In the presentation given by the Inventor at the ADA 59th Annual Meeting June 1999, which is the presentation associated with the Thule (Diabetes) abstract, the slides (e.g., see slides 2 and 3) clearly describe the elements used to construct the Ad/$(GIRE)_3$BP-1 2xfur vector. Specifically, the slides indicate the exact nucleotides of the rL-PK (nucleotides –125 to –173) and rIGFBP-1 (nucleotides –111 to +96) promoter elements used to construct the vector.

Thus, the Thule abstract and the presentation given by the Inventor more than one year prior to the filing of the instant application provided a blue print for making the claimed vector.

Furthermore, the nucleotide sequences of the rL-PK and rIGFBP-1 promoter elements were known in the art. Specifically, Cognet et al. (J. Mol. Biol., 1987) teach the nucleotide sequence of the rat L-type Pyruvate Kinase (rL-PK) gene (see Figure 4), Vaulont et al. teach an element of the rL-PK promoter that is a transcription factor binding site and which includes nucleotides –125 to -173 (see Figure 9), and Goswami et al. teach a promoter region of rIGFBP-1 which includes nucleotides –111 to +96 (See Figure 3A).

Accordingly one of ordinary skill in the art could use the disclosure of the Thule abstract and presentation to know the exact nucleotide sequences needed to make the claimed vector. Furthermore, the actual nucleotide sequences of the rL-PK and rIGFBP-1 genes needed to make the claimed nucleotide sequence was also known in the art (see Cognet et al., Vaulont et al., and Goswami et al.). Thus everything that was required to make the claimed sequence was available more than one year prior to the filing of the instant application. Furthermore, one of ordinary skill would have been motivated to make the vector based on the teaching of the Thule (Diabetes) abstract, and the Thule abstract also provides evidence of an expectation of success.

Therefore, it would have been obvious one of ordinary skill in the art at the time of filing to make the vector of Thule (Diabetes) in view of the presentation(s) presented by Thule and further in view of Cognet et al., Vaulont et al., and Goswami et al., with a reasonable expectation of success.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thule et al (Abstract from meeting June 9-13, 1999, previously cited) in view of Thule and Liu presentation at the ADA 59th Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and further in view of Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Cognet et al. (J. Mol. Biol. 1987, cited by Applicants).

The instant claims are described above.

It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/$(GIRE)_3$BP-1 2xfur (which is an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

To the extent that Thule (Diabetes) does not explicitly teach the actual claimed nucleotide sequences, the claims are obvious in view of the cited prior art for the following reasons.

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In the presentation given by the Inventor at the ADA 59th Annual Meeting June 1999, which is the presentation associated with the Thule (Diabetes) abstract, the slides (e.g., see slides 2 and 3) clearly describe the elements used to construct the Ad/$(GIRE)_3$BP-1 2xfur vector. Specifically, the slides indicate the exact nucleotides of the rL-PK (nucleotides –125 to –173) and rIGFBP-1 (nucleotides –111 to +96) promoter elements used to construct the vector.

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sequence of the rat L-type Pyruvate Kinase (rL-PK) gene (see Figure 4), Vaulont et al. teach an element of the rL-PK promoter that is a transcription factor binding site and which includes nucleotides –125 to -173 (see Figure 9), and Goswami et al. teach a promoter region of rIGFBP-1 which includes nucleotides –111 to +96 (See Figure 3A).

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Therefore, it would have been obvious one of ordinary skill in the art at the time of filing to make the vector of Thule (Diabetes) in view of the presentation(s) presented by Thule and further in view of Cognet et al., Vaulont et al., and Goswami et al., with a reasonable expectation of success.

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736-743), Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Cognet et al. (J. Mol. Biol. 1987, cited by Applicants).

The instant claims are described above.

It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/$(GIRE)_3$BP-1 2xfur (which is an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

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In the presentation given by the Inventor at the ADA 59th Annual Meeting June 1999, which is the presentation associated with the Thule (Diabetes) abstract, the slides (e.g., see slides 2 and 3) clearly describe the elements used to construct the Ad/$(GIRE)_3$BP-1 2xfur vector. Specifically, the slides indicate the exact nucleotides of the rL-PK (nucleotides –125 to –173) and rIGFBP-1 (nucleotides –111 to +96) promoter elements used to construct the vector.

Thus, the Thule abstract and the presentation given by the Inventor more than one year prior to the filing of the instant application provided a blue print for making the claimed vector.

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Accordingly one of ordinary skill in the art could use the disclosure of the Thule abstract and presentation to know the exact nucleotide sequences needed to make the claimed vector. Furthermore, the actual nucleotide sequences of the rL-PK and rIGFBP-1 genes needed to make the claimed nucleotide sequence was also known in the art (see Cognet et al., Vaulont et al., and Goswami et al.). Thus everything that was required to make the claimed sequence was available more than one year prior to the filing of the instant application. Furthermore, one of ordinary skill would have been motivated to make the vector based on the teaching of the Thule (Diabetes) abstract, and the Thule abstract also provides evidence of an expectation of success.

Therefore, it would have been obvious one of ordinary skill in the art at the time of filing to make the vector of Thule (Diabetes) in view of the presentation(s) presented by Thule and further in view of Cognet et al., Vaulont et al., and Goswami et al., with a reasonable expectation of success.

Response to Arguments

2. Applicant's arguments filed 12/16/2008 have been fully considered.

3. With respect to the arguments that the Request for Information under 37 C.F.R. 1.105 is improper, the arguments have been fully considered but they are not persuasive. Applicants argue that the request is late or untimely. Applicants refer to MPEP 704.11(b) in support of their argument. It is pointed out that MPEP 704.11(b) also states, "A requirement may be made at any time once the necessity for it is recognized and should be made at the earliest opportunity after the necessity is recognized." Therefore, Applicants arguments are not persuasive. With respect to the argument that the Information sought does not appear to fit any of the enumerated categories, It is pointed out that 704.11(a) provides specific examples of information reasonably required, including: (I) an explanation of technical material in a publication, such as one of the inventor's publications, (P) other factual information pertinent to patentability, and (Q) the accuracy of the examiner's stated analysis of such items. Therefore, it is not improper to request the information. With respect to the argument that the request does not meet the meet the criteria of reasonable necessity, it is pointed out that the request clearly indicated that the after reviewing the materials of record, additional information was required regarding the Inventors publications and presentation materials to determine if the claimed constructs and the constructs disclosed in the prior art and presentations were the same. Therefore, Applicants arguments are not persuasive.

4. It is noted that no new arguments regarding the rejection of claims under 35 USC 102(b) as being anticipated by the Inventors own publications.

5. It is also noted that the instant action includes new grounds of rejection under 35 USC 103; therefore, the instant action is made non-final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635